



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,562	08/16/2001	Larry D. Paskar	39868/24659	5207

29493 7590 10/20/2004
HUSCH & EPPENBERGER, LLC
190 CARONDELET PLAZA
SUITE 600
ST. LOUIS, MO 63105-3441

EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,562

Applicant(s)

PASKAR, LARRY D.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 20-34, 48, 49 and 52-67 is/are pending in the application.
- 4a) Of the above claim(s) 39-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28 is/are rejected.
- 7) ☐ Claim(s) 1-14, 20-25, 29-34, 48, 49 and 52-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 1.53(b) as follows: The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application), the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. , 1 12. See *Transo Products, Inc.* 7. *Performance Contracting, Inc.*, 38 F.3d 551 , 32 USPQ 2d 1077 (Fed. Cir. 1994).

It is noted that applicant's original specification in the current application is not identical to that in the parent application 08/764,745 or its preceding parent applications. 37 CFR section 1 .53 (5) requires that any new change must be made in the form of an amendment to the prior application as it existed prior to the filing of an application under this paragraph. Applicant's original filed specification in the current application has two new paragraphs at the top of page 4 and two more at the top of page 5 as compared to the original specification of the parent 08/764,745. In addition to being improperly filed, the new paragraphs included in the specification contain information regarding the the use of imaging that is not readily apparent. In addition, applicant's claims contain new language which support is not readily apparent in the parent application. For instance, the claims now require either first and second catheter imaging steps at various shapes or imaging during shaping, neither of which was present in the original specification. While using such imaging techniques may be obvious, as stated in applicant's preliminary comments, inherency requires necessity, which has not been

demonstrated.

This application repeats a substantial portion of prior Application No. 08/764,745, filed 12/12/96, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Specification

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because of the following informalities: Applicant's claim that current specification is a continuation of 08/764,745 when it is in fact a CIP of that application for reasons stated above and further explained below in the arguments sections and the examiner requires a correction for.

Appropriate correction is required.

Claim Objections

Claims 1-14, 20-25, 29-34, 48, 49, 52- 67 are objected to because of the following informalities: The claims are objected to for relying upon a defective claim for priority. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trauthen et al USPN 5,263,928. Trauthen et al. USPN 5,263,928.

Trauthen teaches and inner element in the form of a scope 24 with a marker 81 and an outer catheter 22 with what may be construed as a remote control member in the form of a guidewire 82. It is obvious to track the insertion of the device as it moves along the guidewire during insertion including when the scope is being bent to enter vessels that are at angles to the initial passageway being tracked.

Response to Arguments

The affidavit under 37 CFR 1.132 filed 4-5-2004 is insufficient to overcome the objection of specification based upon an incorrect priority as set forth in the last Office action because: Applicant's arguments as well as the affidavit fail to provide a nexus between that which is claimed and the evidence applicant relies upon to support his contention for continuation and support for the claims in the present application.. First, although it is Dr Beneatti's opinion that each of the listed medical procedures are performed with fluoroscopy, the various procedures listed are far more limiting than the breadth of the general catheterization procedure claimed. Dr Beneatti's provides a

select listing of catheterization procedures (see for instance "selective venous catheterization procedures" and the evidence provided by applicant to support this opinion is dedicated to various forms of dye wherein fluoroscopy is used always to follow the dye injection and sometimes follow the catheter shape. Applicant's claims are broader than this limited class of catheterizations and in fact recite an inner element which may or may not be a fluid transmitting member for dye injection. In addition, applicant claims that the entire combination catheter is imaged, both inner and outer elements, which is not specifically addressed by applicant's specification, the evidence provided or Dr Beneatti's general statements. It is noted that frequently only a radiopaque band or small ring is incorporated in order to navigate using fluoroscopy since the catheter materials are not themselves visible. (See Cho USPN 5,109,830 column 3 lines 35 -47). In other instances the tube itself may be imaged by incorporating a radiopaque material in the catheter to make it visible (see Ganz USPN 4,430,083). Applicant points out (in withdrawn claims 39-47) that the combination catheter itself made of a material that is radiopaque and in the the method claims both inner element and outer catheter are imaged such that the combination catheter shape can be ascertained. However, the parent applications provide no mention of the catheters composition. It is also unclear in that by mentioning the procedures in the parent application whether they were relying upon skilled artisans to make the necessary further modifications to accomplish the tasks. For instance relying upon the readers to incorporate radiopaque markers to specific portions etc. of the catheter, for instance just at the tip as in Ganz to that only the tip make be seen in directing the

Art Unit: 3762

catheter into an opening, or alternatively incorporating a radiopaque substance into only one of the tubular member/inner elements (see Sylvanowicz USPN 5,267,982 column 5 lines 40-49). It is also unclear which of these procedures have vessels that would be large enough to accomplish a reshaping procedure within the passage as claimed. Finally, the general statements of the procedures mentioned in the parent applications could have been referring to other ways the combination catheter could be used for positioning itself in these procedure such as by inserting an optical fiber inside the combination catheter to aim the device to various ostium as in Cho 5,109,830 wherein the device can be steered without imaging the catheter itself, even though applicant's specific claims do not envision such an embodiment now.

Applicant instead relies upon a generalized statement that his device may be used in various procedures without providing details anywhere close to the specificity of the method steps now claimed. It is therefore concluded that applicant's disclosure in the parent application, did not provide ample support for what is being claimed at this time.

Election/Restrictions

This application contains claims 39-47 drawn to an invention nonelected with traverse in Paper No. 2-19-2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

October 16, 2004


MARK BOCKELMAN
PRIMARY EXAMINER